K093975

Appendix A: **510(k) Summary: Simpler Toadstool Abutments**

DATE OF PREPARATION: Tuesday, June 01, 2010

ADMINISTRATIVE INFORMATION

JUN - 4 2010

Manufacturer: Pan Global Implant Corp.
#404 1023 Wolfe Ave.
Vancouver, BC, Canada
V6H 1V6
Telephone: 604 736 9890
Fax: 604 736 9747
E-Mail simpler@simplerimplants.com

Official Contact Dr. Harold Bergman or Mrs. Karen Bergman
Address: same as above

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	Simpler Toadstool Abutment
Common Name	Dental implant o ring abutment
Classification Regulations:	Endosseous dental implant abutment 21 CFR 872.3630, Class II
Product Code	NHA
Classification Name	Endosseous Dental Implant Abutment
Reviewing Branch:	Dental Devices Branch

SUBSTANTIAL EQUIVALENCY TO MARKETED PRODUCT: As with most O Ring Abutment systems on the market today, the substantially equivalent predicated marketed devices include the use of a ball abutment, O rings, keepers, compatibility with the company's implants, intended use, indications for use and safety standards. **Camlog K051636, Bicon K853733, Biomet and BioHorizons K990277, Implant Innovations K891613** are all approved O ring abutment systems which have proven safe and effective and substantially equivalent to the Simpler Toadstool Abutments.

There are two modifications to the traditional O ring Abutment design used by the predicate devices. The top portion of the Simpler Toadstool Abutment has a flattened ball giving the retention area an ovoid appearance in profile. The external hexagonal portion of the abutment that allows the abutment to be torque into the implant from below the ball at gingival level and incorporated as part of the ovoid ball. These two changes effectively lower the profile to of the abutment to 0.098" above the gingiva. A rubber O ring is inserted into a metal keeper which in turn is imbedded into the denture base as with predicate devices.

The attachment portion of the Simpler Toadstool abutments are identical in all design aspects to the attachment portion of the Toadstool Mini Narrow Diameter implant K092674. The mating surface

portion inserted into the implant is identical in all aspects to the mating surface portion inserted into the implant of the Simpler O ring Abutments and other Simpler Abutments.(i.e. Simpler Implants K974403, K060376, K974404, K974403). The in denture attachment portion of the Simpler Toadstool abutments are equivalent to the in denture attachment portion of the Simpler predicate devices listed above. All Simple Implant Abutments have the same Quality System (ISO 13485: 2003).

(i.e. Camlog K051636)

DEVICE DESCRIPTION: The Toadstool abutment is a restorative prosthesis that threads into an already integrated dental implant. A rubber O ring snaps into a metal keeper, both of which are imbedded into a denture base. When in use, this rubber ring/keeper combination attaches the denture to the abutment preventing the movement of the denture while providing a cushioning affect to the implant.

It has a flattened ball at the top giving the retention area an ovoid appearance in profile. The external hexagonal portion of the abutment that allows the abutment to be torqued into the implant has been moved from below the ball at gingival level to the be part of the ovoid retention portion

INDICATIONS:

The Simpler Toadstool Abutment consists of a pre-manufactured flattened ball which is directly screwed into a Simpler endosseous dental implant. The design allows for a lower profile height for a soft tissue supported overdenture. This prosthetic device is indicated for retention of soft tissue supported overdentures only and NOT for implant supported prostheses such as crowns and bridges.

TECHNOLOGICAL CHARACTERISTICS: There are two modifications to the traditional O ring Abutment design used by the predicate devices. Instead of the traditional rounded ball, the top portion of the Simpler Toadstool Abutment has a flattened ball giving the retention area an ovoid appearance in profile.

Instead of the hexed shaped torquing portion of the abutment lying below the ball at the gingival level, the external hexagonal portion of the abutment that allows the abutment to be torque into the implant is moved and incorporated as part of the ovoid ball. These two changes effectively lower the profile to 0.098" above the gingival.

The neck portion of the abutment below the ball has been narrowed and elongated to allow the rubber ring and keeper to move apically thereby reducing the load on the implant when in function.

NON CLINICAL TESTS: The torquing load on an abutments when inserting the abutment into the implant is recommended not to exceed 30NCm. The abutments have been tested to a breaking limit of 113 to 120 NCm. This limit is well in excess of recommended torque loads.

CONCLUSIONS OF TESTS: The only major change from equivalent predicated devices is the movement of the torquing hex from below the ball and incorporating it as part of the ball itself. The recommended forces (30NCm) used to tighten the abutment into the implant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN - 4 2010

Dr. Harold Bergman
Pan-Global-Implant
#404 1023 Wolfe Avenue
Vancouver, BC
Canada V6H 1V6

Re: K093975
Trade/Device Name: Simpler Toadstool Abutment, Model S19000-S19009
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: May 14, 2010
Received: May 18, 2010

Dear Dr. Bergman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K093975**

Device Name: **Simpler Toadstool Abutnent**

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Prescription Use Yes AND/OR Over-The-Counter Use No
Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

R Rotz DDS for Dr. K.P. Mulay

vision Sign-Off)

vision of Anesthesiology, General Hospital

fection Control, Dental Devices

)(k) Number: K093975